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November 11, 1999

Assistant Commissioner for Patents Box Patent Application Washington, D.C. 20231

Re:

MICRODERMABRASION DEVICE

Docket No. 032-26-001

Sir:

Transmitted herewith for filing under 35 U.S.C. 111 and 37 CFR 1.53 is the patent application of STEPHEN H. WALDRON entitled MICRODERMABRASION DEVICE.

Enclosed are:

14 pages of written description, claims and abstract.

4 sheets of drawings plus 2 copies.

An Assignment of the invention to ALTAIR INSTRUMENTS INC...

Executed Declaration and Power of Attorney.

Small Entity Statement

The filing and recording fees have been calculated as shown below:

Basic Fee			\$380.00
Total Claims	(16 - 20)	x \$9.00 =	0.00
Independent Claims	(2-3)	x \$39.00 =	0.00
Assignment Recording Fee			40.00
	Total Fee:		\$420.00

Our Check No. 14153 for \$420.00 to cover the filing and recording fees is enclosed. We authorize the Commissioner to charge (1) payment of any additional filing fees required under 37 CFR §1.16, (2) payment of any patent application processing fees under 37 CFR §1.17 associated with this communication, or (3) payment of any fees that occur during the pendency of this application (and to credit any overpayment) to Deposit Account No. 11-1580. We enclose a duplicate copy of this sheet.

> Very truly yours, KOPPEL & JACO

Michael J. Ram

Registration No.26,379

RSK/mm Enclosures Transmittal ltr.doc

15.00

Docket No. 032-26-001 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: STEPHEN H. WALDRON

Title: MICRODERMABRASION DEVICE

VERIFIED STATEMENT CLAIMING SMALL ENTITY STATUS

I, STEPHEN H. WALDRON, declare: I am the President of ALTAIR INSTRUMENTS INC.

and am authorized to make this Statement. ALTAIR INSTRUMENTS INC. qualifies as a small

business concern as defined in 13 C.F.R. §121.3-18, and reproduced in 37 C.F.R. §1.9(d), for purposes

of paying reduced fees under 35 U.S.C. §41(a) and (b), in that the number of employees of the

concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement,

(1) the number of employees of the business concern is the average, over the previous fiscal year of the

concern, of the persons employed on a full-time, part-time or temporary basis during each of the pay

periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or

indirectly, one concern controls or has the power to control the other, or a third party or parties

controls or has the power to control both.

All rights under contract or law have been conveyed to and remain with ALTAIR

INSTRUMENTS INC. with regard to the invention entitled "MICRODERMABRASION DEVICE",

which is Docket No. 032-26-001 in the files of ALTAIR INSTRUMENTS INC. 's lawyers KOPPEL &

JACOBS. The application is filed with this Statement.

ALTAIR INSTRUMENTS INC. acknowledges the duty to file, in this application or the patent

issuing on this application, notification of any change in status resulting in loss of entitlement to small

entity status before paying, or at the time of paying, the earliest of the issue fee or any maintenance fee

which is due after the date on which status as a small entity is no longer appropriate. (37 C.F.R.

§1.28(b)).

I declare further that all statements made herein of my own knowledge are true and that all

statements made on information and belief are believed to be true. These statements were made with

the knowledge that willful false statements and the like so made are punishable by fine or

imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize

the validity of the application or any patent issuing from this application.

Date: Nov 11 1999

STEPHEN H. WALDRON

566 Avocado Place

Camarillo, California 93010

M2-032-26-001ses.

THE CHARLES OF THE CONTRACTOR OF THE PROPERTY OF THE PROPERTY

APPLICATION

OF

STEPHEN H. WALDRON

FOR

UNITED STATES LETTERS PATENT

ON

MICRODERMABRASION DEVICE

Docket No. 032-26-001

Assigned to

ALTAIR INSTRUMENTS INC.

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MICRODERMABRASION DEVICE

Background of the Invention

This invention provides a treatment tool and tissue collection system for remove of outer layers of skin to provide a revitalized, fresh skin surface. This objective is to remove dead and old skin cells without damaging the remaining skin surface and without the use of powdered abrasive materials because these materials may result in undesirable side effects.

10 Description of the Prior Art

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Dermabrasion, also referred to as microdermabrasion, is a process for removal of dead cells from the outermost layer of the skin, referred to as the epidermis, clean out blocked pores, and enhance skin tone. Additionally, the margins of acne scars and other traumatic scars can be erased and aging spots and sun damaged skin can be polish off. This must be accomplished without injuring the lower two layers, namely, the dermis and the subcutaneous layer or lower dermis. Typically, the skin surface is treated a minimum of 5 times spaced 7 to 10 days apart. This is then followed by periodic maintenance sessions. The benefits are:

- 1. poor, dull skin is enhanced by a gentle resurfacing of the superficial skin layers,
- expression lines typically seen on the forehead and around the mouth are softened,
- fine, crepey lines on the cheeks, generally caused by aging and sun damage are reduced,
- 4. pigment changes and skin discoloration are reduced,

- enlarged pores are reduced and clogged pores typical in acne conditions are exfoliated and cleaned out, and
- 6. margins of superficial acne marks, stretch marks, burn scars and surgical scars can be smoothed.

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Use of abrasion techniques can be traced back to the ancient Egyptians who used alabaster and pumice to remove blemishes and rough spots and to make the skin smooth and soft. More recently, abrasive tipped devices or rotating brushes and cylinders coated with abrasive particles, such as diamond dust, have been used to remove skin layers (US Patent 2,712,823; US Patent 2,867,214; US Patent 2,881,763; US Patent 2,921,585). US Patent 5,800,446 describes a stick, glove finger tip or glove palm coated with an abrasive material which is rubbed over the skin surface to provide a polishing action. US Patent 3,964,212 directed to a pneumatic grinding machine for flat surfaces, incorporates a rotating grinding tool enclosed in a housing with air flowing over the surface to collect dust created by the grinding operation. US Patent 4,378,804 is directed to a skin abrasion device which uses flowing water to rotate an abrasive brush and create a vacuum to remove loosened skin particles. The rotating brush is usually used in conjunction with a liquid detergent or medicinal compound applied to the skin surface being scrubbed. Chemicals, ultrasonic oscillating tips (US Patent 5,012,797) and lasers have also been used for amore aggressive abrasion. US Patent 5,037,431 describes the use of a pressurized jet of a liquid, such as water or sterile saline, to fragment and remove diseased tissue without harming surrounding healthy tissue. This device operates in conjunction with vacuum aspiration to remove the liquid and fragmented tissue.

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The present trend is to abrade the skin surface using powdered aluminum oxide or a liquid topical composition containing suspended aluminum oxide (US Patent 4,957,747). US Patent 5,037,432 provides for the pressurized delivery, using compressed air, of a powdered, abrasive substance and the removal of the abrasive substance and loosened skin tissue using a vacuum. The abrasive substance is typically microcrystals of quartz, metal, or aluminum oxide. The powdered abrasive is blown through a wand which has a hole in the skin contact end to provide access of the abrasive to the skin surface being treated. An alternative is to cause the aluminum oxide powders to flow by applying a vacuum to the exhaust side of a container holding the abrasive powder and entraining the powder in a flowing gas stream. The powder is then drawn by the vacuum through a treatment tool, across the skin surface to abrade or rub off the epidermis and then recovered along with the skin particles in a collection chamber (US Patent 5,100,412; US Patent 5,207,234; US Patent 5,810,842). This process is similar to "bead-blasting". A potential disadvantage of all of these techniques is that particles can be lodged in the skin and a substantial amount of aluminum oxide and cells, which have to be properly disposed of, may be left behind on or in the skin.

While no toxic effects have been shown from aluminum oxide left on or in the skin, this material has been shown to cause inflammatory changes to the lungs in workers who have inhaled aluminum oxide. (Schwarz,Y, et al., "Evaluation of Workers Exposed to Dust Containing Hard Metals and Aluminum Oxide" Am J of Ind Med, 34(20;177-82) 1999 Aug,). Also, the eyes must be protected from the highly abrasive dust, which can injure the cornea. Therefore, it is recommended that workers using these devices wear breathing masks and glasses to provide protection from ophthalmic and respiratory damage. Similar protection is suggested for patients being

treated. It is also possible that particles of the abrasive material can be left imbedded in the skin surface resulting in long term irritation and provide a situs for bacterial infections.

Summary of the Invention

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The device for microdermabrasion comprises a hollow tube with and abrasive material permanent attached to a skin contacting end. The abrasive coated tip is moved over the skin surface while a vacuum is applied through the tube to the skin surface to remove cells abraded from the skin surface. The vacuum also causes the skin to be held in intimate contact with the abrasive tip during the treatment procedure.

Description of the Figures

FIGURE 1 is a schematic drawing of a device incorporating features of the invention.

FIGURE 2 is a partial cutaway view of a treatment tube and filter assembly used in the device of Figure 1.

FIGURE 3 is a schematic drawing of the vacuum flow path of the device of Figure 1.

FIGURE 4 is a cutaway side view of the end of the treatment tube.

FIGURE 5 is an enlarged view of the circled portion of Figure 5A.

FIGURES 6A and 7A, are cutaway side views of two different treatment tubes usable with the device of Figure 1.

FIGURES 6B and 7B are end views of the two different treatment tubes of Figures 6A and 7A.

FIGURE 8 is a cutaway side view of the end of a sloped treatment tube.

FIGURE 9 is a cutaway side view of the end of a tapered treatment tube.

FIGURE 10 is a cutaway side view of a valved treatment tube.

FIGURE 11 is a cutaway side view of the end of a treatment tube with a second tube for delivery of a supplemental treatment fluid.

FIGURE 12A is a side cutaway side view of the end of a treatment tube with an enlarged, sloped end.

FIGURE 12B is an end view of the treatment tube of Figure 12A.

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FIGURE 13 is a side cutaway side view of the end of a treatment tube with an enlarged, sloped concave end.

FIGURE 14A is a view of a rectangular shaped treatment surface with the handle being the conduit for the vacuum.

FIGURE 14B is a cutaway side view of the end of a treatment tube with an enlarged, rectangular shaped end.

Detailed Description of the Invention

The invention provides the capability to perform microdermabrasion without the potential health risks or hazards of using a flowing, powdered metallic substance such as aluminum oxide. This is generally accomplished by the use of a tube having a treatment tip with an abrasive material permanently attached thereto. The term "tube" or "tubular" used herein refers to an elongated hollow structure of any cross section, which includes, but is not limited to, a round, oval, square or rectangle cross section. The abrasive coated end piece, which may also have various different shaped cross sections, may be secured to the treatment tip or be removable and interchangeable. The abrasive tip is rubbed over the skin surface being treated. The tube and related instrumentation also provides a vacuum collection and an optional filter system for collection of the skin cells removed by the procedure, the skin cells being aspirated through a hole or holes in the central portion of the abrasive tip. The vacuum also aids in making an intimate contact between the skin and the abrasive coated tip.

Figure 1 shows the overall system which comprises a housing 10 which encloses a vacuum pump 24, an ON/OFF switch 12, a gauge 14 to measure the level of vacuum and a valve 16 to adjust the vacuum. While not necessary for operation of the invention, shown mounted on the external surface of the housing 10 is a filter assembly 18. Attached to the filter assembly 18 is a hollow tube or wand assembly 20

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upon which the treatment tip 22 is mounted. The other end of the filter assembly 18 is connected to the vacuum pump 24 located inside the housing 10.

Figure 2 shows the wand assembly 20 comprising tubing 26 connecting the tip 22 and filter assemble 18. Within the filter assembly 18 is a filter pad 28 which collects the loosened skin tissue and prevents the skin tissue or collected body fluids and oils from entering the vacuum pump. The various different tips 22 are discussed in detail herein below. The tubing 26 is flexible so that it is easy to manipulate the tip and to allow ready connection of the wand assembly 20 to an upper hollow extension 30 on the external surface of the filter assembly 18 and a connector tube 32 on the tip. Since the system uses vacuum, the connections are self-sealing.

A lower hollow extension 34 extending from the filter assembly 18 fits into a matching hole on the main housing. 10. The filter assembly 18 is easily removable so that it can be replaced after each patient and disposed of. The filtration pad 28 inside the filter housing 18 catches the debris but allows air to easily flow through the pad. The lower hollow extension 34 allows air pulled through the filter assembly 18 to be drawn into the vacuum pump 24.

Figure 3 shows the flow of the air stream through the vacuum system. It comprising a vacuum pump 24, filter assembly 18, tubing 26 which connects the filter to the treatment tip 22 and vacuum line 36 connecting the filter assembly 18 to the vacuum pump 24. The vacuum pump 24 is operated at a fixed speed to produce a fixed vacuum level. To control the level of vacuum applied through the treatment tip 22 to the skin, a valve 16 vents air into the system, thus reducing the amount of vacuum. Gauge 14 allows the level of vacuum to be monitored. Of course, the vacuum pump can be operated at different speeds to change the level of vacuum applied.

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Referring to Figure 2, a vacuum is applied through the tube 26 to a hole 38 in the treatment tip 22. The tip 22 is brought into contact with skin, the vacuum causing the skin to be pressed against a roughened surface on the end 40 of the treatment tip. As the tube is manually moved across skin the roughened surface abrades the epidermis dislodging cells from the surface. The vacuum causes the dislodged cells to flow into the wand assembly 26. The level of abrasion depends on the level of vacuum applied to the treatment tip and the size of the abrasive particles attached to the treatment tip.

Figure 4 is a side view of the working end of the treatment tube 22. The end of the treatment tube 22 has diamond grit 42 preferably adhered to the end of a metal tube by a plating process using nickel 44 as a binder. The nickel 44 is applied in a controlled manner so that sufficient nickel is present to hold each piece of diamond in place, but yet allow a faceted portion of the diamond to be exposed, the sharp edges of the diamond providing the cutting edges. A diamond particle size of around 0.0035 inches (63-75 microns) produces a smooth and uniform removal of skin surface. However, diamond particles from about 50 to about 150 microns can be used to produce different levels of abrasion, the larger particles removing more skin cells and performing the cell removal more rapidly. However, if the particles are to large the dermis can be damaged and injury to the second and third layers of skin can occur. Very fine particles remove few skin cells and act more in a polishing manner. Other abrasive materials, such as aluminum oxide, can be bonded to the treating tool tip or the tip itself can have a roughened surface cut into the end thereof. Use of an adhered aluminum oxide of about 100 grit (151 µ) provides a coarse (aggressive) treatment, and use of about a 120 grit (127µ) material provides a medium level of treatment. Particles with a higher grit (i.e. small size particles) would create more of a polishing

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effect. Of course, many different hard abrasive materials known to those skilled in the art, such as silicon carbide, silicon oxide, and various metal nitrates can be used in place of the diamond or aluminum oxide.

The dimensions and materials used to construct the wand assembly 20 is not critical. However, a preferred treatment tip 22 is formed from a 12mm OD stainless steel tube with a 6mm ID and a diamond coated end. The stainless steel/ diamond tool can be steam or chemical sterilized between uses without damage. A first alternative would be to have a single use or single patient tube which is made of plastic, the end being coated with aluminum oxide, or similar abrasive materials. The abrasive can also be adhered with an adhesive. A further alternative would be a tube, which could be stainless steel, plastic or other stiff tubular material, with a suitable removable and replaceable tip or a tip with an abrasive end surface formed by a machining process.

Figure 6a shows a removable disc 46 sized to fit over the end 40 of the tube 22. The disc 46 has an abrasive end or abrasive material attached to its outer end. During the procedure various disc with different abrasive characteristics can be interchanged and at the conclusion of the procedure the disc(s) 46 can be discarded.

The end of the tube can also be made abrasive by machining the surface as shown in Figures 7a and 7b in a manner commonly called knurling. Diamond shaped projections 48 are raised on the surface for abrading in any direction. This would be similar to the construction of wood and metal files. The tip as shown in Figure 7b can also be provided which raised portions tapered and oriented in only one direction, similar to a saw teeth, except the tooth would only be a few thousands of an inch high, to achieve smooth abrading of the surface.

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Besides providing different means of abrasion on the end of the treatment tip 22, the contour or shape of the tip can be varied. Figures 6a and 7a show a flat end. The flat end can provide a greater surface area in contact with the skin for an aggressive removal of surface cells. A concave surface as shown in Figure 4, in conjunction with the vacuum applied to the skin surface results in a more uniform cutting surface on the skin. For easier access to difficult to reach locations the roughened ends can be sloped, as shown in Figure 8, or tapered, rounded or cone shaped, as shown in Figure 9, to better treat curved surfaces, such as the area between the cheek and the nose.

The device uses a vacuum pump 24 which generates a constant level of vacuum, which is controlled (lessened) by the venting of air into the system by the valve 16 mounted in the housing 10. As an alternative, the full vacuum can be applied to the wand assembly 20. The level of vacuum can then be decreased by air vented into the system through vent hole 50 by adjusting flow control valve 52 mounted on the wand 20 or treatment tube 22, as shown in Figure 10. The valve 52 can be configured to be a simple on/off control or variable so that suction can be readily

adjusted by the operator while performing the procedure.

While the treatment tube can be used alone to abrade the skin and the vacuum system can be configured to primarily pick up the loosened skin cells, it has been found that applying the vacuum through the hole 38 in the end of the treatment tip 40 provides an unexpected advantage. The skin being treated is pulled against the abrasive tip, thus increasing the effectiveness of the tissue abrasion and removal process. Sealing off ambient air raises the level of vacuum and makes the abrasion more aggressive. The concave tip as shown in Figure 4 is particularly effective when

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used in conjunction with a vacuum, as it provides a larger surface area for the skin/abrasive material contact.

As a further variation, the treatment tip 22 can have an enlarged abrasive coated end 56, 58 which is flat and slopped or sloped and concave such as shown in Figures 12A and 13 respectively. While a single hole 38 in the center of the end 56 may be used for applying the vacuum, the efficacy of the abrasive tip can be improved by using several holes 38 therein Figure 12B is an end view showing an example of a flat, sloped abrasive tip with multiple openings for application of the vacuum to the skin surface. An end view of the concave tip of Figure 13 would have a similar appearance. Further, while Figures 12A and 13 show the end to be part of the treatment tip 22 it could be a separate removable piece as shown in Figures 6a and 6b. These configurations have particular utility in treating large flat body surfaces such as the chest, back and legs of an individual. They can also be used where a large abrasive treatment surface is desired but it is preferential to spread out the applied vacuum so that it does not aggressively suck skin into the tip or suck the skin into the tip at a single point.

Figure 11 shows a second tube 54 mounted on the treatment tip 22. The tube could be used to allow the metered use of chemicals to enhance the abrasion or supply or other liquids to reduce friction.

To use devices embodying the invention the vacuum is applied, through the treatment tool, to the area of the skin to be treated while the abrasive surface, which surrounds the applied vacuum, is moved over the skin surface to be treated. The abrasive tip is typically moved over the skin surface in a circular motion. However, a combination of vertical and horizontal movements of the tip, with or without the circular movements, may also be used to assure that the skin area is uniformly treated. Also, if

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a particular skin blemish or abnormality is to be treated. The tip motion can be restricted to that particular portion of the skin.

Figures 14A and 14B show an elongated treatment end with a large central opening 59 for application of the vacuum to the skin. In this case the device has wide treatment, shaded like a razor, and elongated abrasive areas for debrading flat areas of skin.

While the invention has been shown and described with reference to different embodiments thereof, it will be appreciated by those skilled in the art that variations in form, detail, compositions and operation may be made without departing from the spirit and scope of the invention as defined by the accompanying claims.

For example, the vacuum does not have to be provided by a vacuum pump with controller housing but can be provided by a centrally located vacuum system such as may be available in a hospital or medical facility. However, to prevent contamination of the vacuum system the filter assembly should be provided to collect the tissue removed. The abrasive tip has been described as formed by adhering or attaching an abrasive material t thereto or machining the surface of the tip to create a roughened surface. However, one skilled in the art will recognize that there are numerous chemical and mechanical processes to create a roughened surface on the end of the treatment tip sufficient for performing the process described herein.

I claim:

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- 1. A device for removing portions of the outer layers of skin comprising: a source of a vacuum, and a tube with an abrasive treatment tip thereon, the tube being attached to the source of
- vacuum so that a lumen through the tube has a reduced pressure therein which is less than the ambient pressure surrounding the tube, the abrasive tip having at least one opening therein for applying the reduced pressure within the tube to a skin surface.
- 2. The device of claim 1 wherein the source of vacuum is a vacuum pump enclosed within a housing, the housing have means thereon for monitoring and controlling the level of vacuum delivered.
 - 3. The device of claim 1 further including means for varying the level of reduced pressure applied through the treatment tip.
- 4. The device of claim 3 wherein the means for varying the level of reduced pressure applied through the treatment tip is a valve mechanism mounted in the treatment tube
- 5. The device of claim 3 wherein the means for varying the level of reduced pressure applied through the treatment tip is a valve mechanism in operative connection to the source of vacuum.
- 6. The device of claim 1 wherein the abrasive tip has diamond particles attached thereto.
 - 7. The device of claim 1 wherein the abrasive tip has a mechanically or chemically created roughened surface.
 - 8. A tubular device for performing micro-abrasion of a skin surface comprising a tubular device with a lumen there through, the tubular device having a first end with an abrasive surface and means on a second end thereof for attachment to a source of a vacuum.
 - 9. The tubular device of claim 8 wherein the abrasive surface on the first end comprises crystalline diamond pieces permanently secured to said first end.
- 10. The tubular device of claim 8 wherein the abrasive surface on the first end comprises crystalline aluminum oxide pieces permanently secured to said first end.

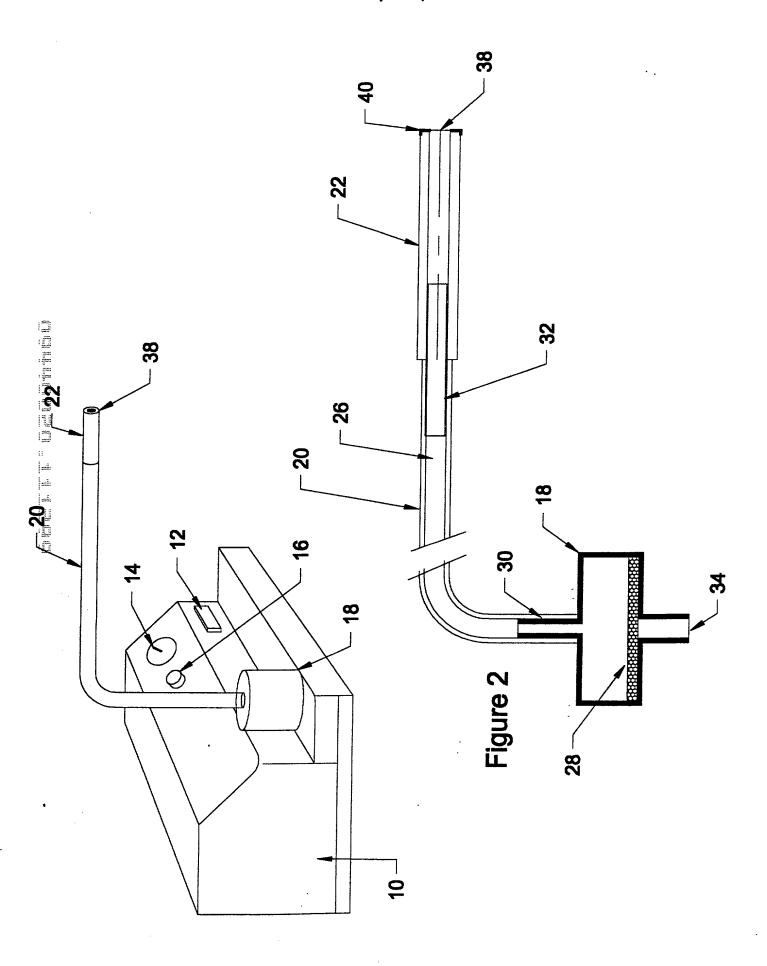
ABSTRACT OF DISCLOSURE

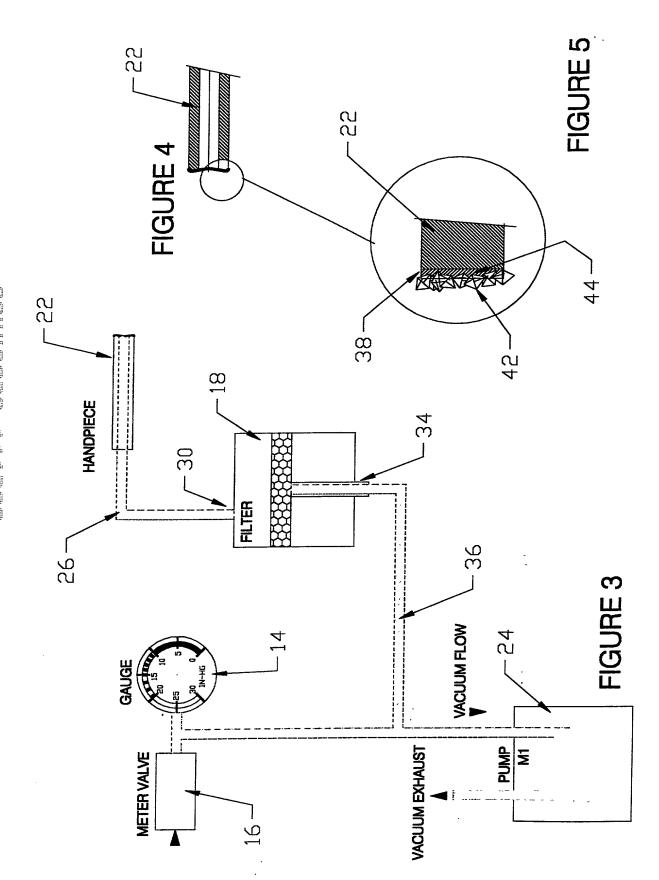
This invention provides a treatment tool and tissue collection system, for remove of outer layers of skin to provide a revitalized, fresh skin surface, and a method of using same, comprising a abrasive tipped tool mounted on the end of a tube, said tube being connected to a source of vacuum. The vacuum aids in maintaining intimate contact between the abrasive tip and the skin during the treatment process and transports the removed tissue to a collection container.

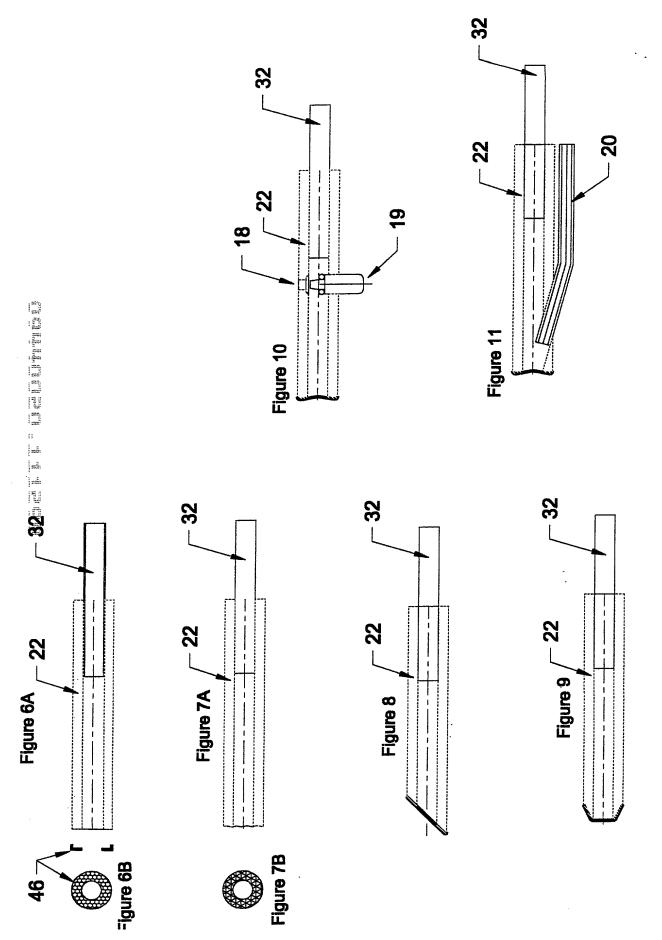
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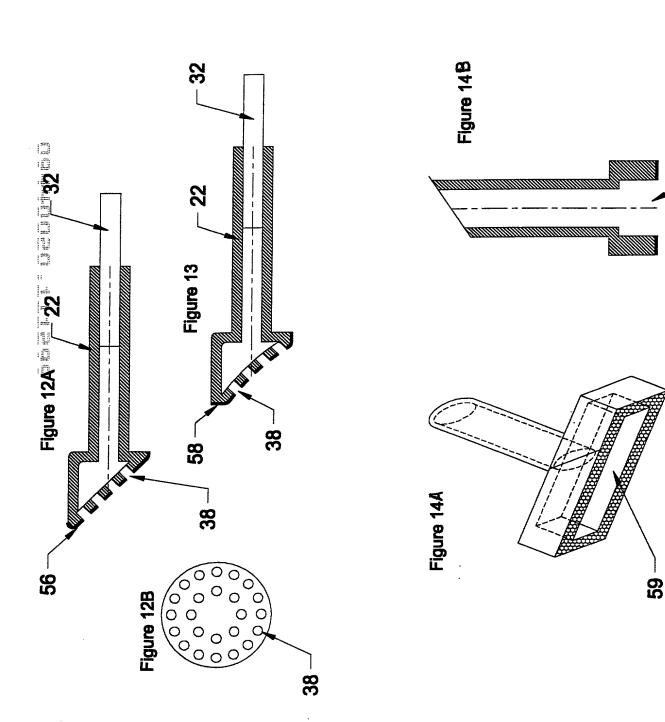
M2-W032-26-001PAT







. 59



DECLARATION, POWER OF ATTORNEY AND STATEMENT CLAIMING SMALL ENTITY STATUS

I, STEPHEN H. WALDRON, declare: I am a citizen of the United States of America, residing at 566 Avocado Place, Camarillo, California 93010. I believe I am the original, first and sole inventor of the invention entitled "MICRODERMABRASION DEVICES" described and claimed in the attached specification. I have reviewed and understand the contents of the specification, including the claims. I acknowledge a duty to disclose information of which I am aware that is material to the examination of this application in accordance with 37 C.F.R. \$1.56(a).

SMALL ENTITY STATUS STATEMENT

I further declare that I qualify as an independent inventor as defined in 37 C.F.R. \$1.9(c) for purposes of paying reduced fees under 35 U.S.C. \$\$41(a) and (b) to the Patent and Trademark Office with regard to this invention.

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 C.F.R. \$1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 C.F.R. \$1.9(e).

I acknowledge the duty to file, in this application or the patent issuing on this application, notification of any change in status resulting in loss of entitlement to small entity status before paying or at the time of paying the earliest of: (1) the issue fee or (2) any maintenance fee, which is due after the date on which status as a small entity is no longer appropriate. (37 C.F.R. §1.28(b))

I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true. These statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001, and that such willful false statements may jeopar-

dize the validity of this application or any patent issuing from this application.

POWER OF ATTORNEY

I hereby appoint Richard S. Koppel (Reg. No. 26,475) and Michael J. Ram, (Reg. No. 26,379) whose address is:

KOPPEL & JACOBS

555 St. Charles Drive, Suite 107 Thousand Oaks, California 91360 Telephone (805) 373-0060

my attorneys with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected with the application.

Wherefore, I subscribe my name to the foregoing specification, claims and declaration.

Date: 1000 11 , 1999

Post Office Address:

STEPHEN H. WALDRON 566 Avocado Place Camarillo, CA 93010

M2-032-26-001dec.pa